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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,534	06/22/2005	Jun Mori	123680	1629

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
06/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,534	MORI ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,8,11 and 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6,8,11 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/18/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/18/10 was filed after the mailing date of the previous Office Action on 9/04/09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Terminal Disclaimer

The terminal disclaimer filed on 3/24/10 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/579,055 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

Claim 17 is objected to because of the following informalities: the claim recites "tartaric acid", but misspells the term tartatic acid. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 6, 8, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Uchiumi et al (JP 10-279480 hereafter '480) in view of Koide et al (JP 10-265373 hereafter '373).

The '480 patent discloses a topical drug formulation comprising 3-methyl-1-phenyl-2-pyrazolin-5-one in combination with well known excipients (abstract). The formulation comprises water soluble polymers such as polyvinylpyrrolidone, and starch, polyhydric alcohols such as ethanol, and a mass of water [0013-0014]. The reference is silent to the concentrations of the carrier formulation however the active compound is present up to 50% of the composition (abstract).

Topical carrier formulation are fairly well known in the art whether rubber or aqueous based, the components are well know and common in the art. This can be seen in the '373 and '132 patent. The prior art provides a wide range of active agents combined into topical formulations that can be either aqueous based or rubber based.

The '373 patent discloses a tacky adhesive composition comprising a drug, water-soluble polymer, cross-linking agent a polyhydric alcohol and water (abstract). The water soluble polymers include polymers such as polyacrylates including sodium polyacrylates, Carbopol, cellulose polymers, xanthan, and alginates, [0010, 0012-0020], and these polymers make up 1-15% [0014]. The formulation comprises crosslinking agents that make up from 0.1-10% of the formulation and include glycine [0017-0019]. The formulation includes aluminum hydroxide [0016]. The formulation comprises polyhydric alcohols such as ethylene glycol and propylene

glycol that make up from 15-50% of the formulation [0020-0021]. The formulation further comprises tackifiers such as cellulosic resins, where the compounds are present in the formulation up to 15% [0020]. The water content of the formulation ranges from 40-70% [0038]. The drugs range from 0.001-10% of the drug formulation [0031] and can range from anti-inflammatory agents to muscle relaxants and vitamins [0030-0031]. These compounds are useful for treating diabetes, cancer, pain or as a sun-block [0029]. The tacky formulation is applied to a film or substrate and applied to the skin [0022].

Regarding claim 11, it is the position of the Examiner that the product claim, while reciting method of use limitations, is merely a product claim. The method of use limitations are merely future intended use limitation that do not distinguish over the prior art. The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945) "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.). See also In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) (selection of a known plastic to make a container of a type made of plastics prior to the invention was held to be obvious); Ryco, Inc. v. Ag-Bag Corp., 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988). In the instant case the same components are combined in the same way, in the same concentrations.

Regarding the specific ranges of the instant claims it is the position of the Examiner that such limitations are obviated by the proposed combination. The general conditions of the claims have been met with each result effective parameter being met by the prior art. A transdermal

formulation comprising an aqueous base comprising a water soluble polymer, a polyhydric alcohol, a crosslinking agents and a mass of water is disclose aqueous the prior art. The carrier formulation of the '373 patent is similar enough to the instant claims that any modifications would be obvious to one of ordinary skill in the art, as a result of routine experimentation. The formulation would comprise the same components and be used for the same purposes including arteriosclerosis. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

It would have been obvious to combine the compound of the '480 patent into the topical preparation of the '373 patent in order to improve the transdermal delivery of the '480 compound. The carrier formulations would have provided a transdermal with reduced skin irritation and improved drug permeability. One of ordinary skill in the art would have been motivate to make this combination with an expected result of stable percutaneous formulation useful in treating skin tissue disturbances.

Claims 1, 3, 6, 8 and 15-17 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Uchiumi et al (JP 10-279480 hereafter '480) in view of Mori et al (USPN 6,248,350 hereafter '350).

The '480 patent discloses a topical drug formulation comprising 3-methyl-1-phenyl-2-pyrazolin-5-one in combination with well known excipients (abstract). The formulation comprises water soluble polymers such as polyvinylpyrrolidone, and starch, polyhydric alcohols such as ethanol, and a mass of water [0013-0014]. The reference is silent to the concentrations of the carrier formulation however the active compound is present up to 50% of the composition (abstract).

The '480 patent differs from the instant claims in that it is silent to the inclusion of the specific excipients of the instant claims. These components are known in the art of percutaneous drug formulations as can be seen in the '350 patent. The '350 patent discloses a percutaneous formulation comprising a drug compound, water soluble polymers such as sodium polyacrylates in a concentration of about 20% (col. 6, lin. 45-60); polyhydric alcohols such as glycerin in a concentration of about 10% (col. 5, lin. 45-55); crotamiton in a concentration of about 5% (col. 5, lin. 15-20); N-methyl-2-pyrrolidone in a concentration from 0.5-10% (col. 6, lin. 20-25); tartaric acid (Example 1); and water in a concentration of 20% (col. 5, lin. 40-44). It would have been obvious to include the dug compound of the '480 patent into the percutaneous formulation in order to provide a stable topical delivery.

It would have been obvious to combine the compound of the '480 patent into the topical preparation of the '373 patent in order to improve the transdermal delivery of the '480 compound. The carrier formulations would have provided a transdermal with reduced skin

irritation and improved drug permeability. One of ordinary skill in the art would have been motivate to make this combination with an expected result of stable percutaneous formulation useful in treating skin tissue disturbances.

Response to Amendment

The Declaration under 37 CFR 1.132 filed 3/3/10 is insufficient to overcome the rejection of claims 1, 3, 6, 8, 11,and 13-17 based upon 103(a) as set forth in the last Office action because: The declaration tests Example 1 of the instant specification with the closest prior art, however the formulation represented by Example 1 is not commensurate in scope with the instant claims. The formulation comprises 11 components, while the composition of the instant claims only comprises 5 ingredients. Though the tested formulation shows a distinction over the closest prior art, this formulation is not represented in the instant claims, and for this reasons the Declaration is insufficient to overcome the prior rejections.

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 6, 8, 11, and 13-17 have been considered but are moot in view of the new ground(s) of rejection. However the '480 patent continues to disclose a topical formulation that would result in percutaneous absorption of the drug compound. Further in addition to oral and intravenous formulation, topical cream formulations are also disclosed. These would result in percutaneous, through the skin absorption. Although the specific concentration of the instant claims is not taught, it would have been obvious to optimize the concentrations as seen in the '373 patent. Applicant argues that the

Declaration provides evidence of patentable distinction, however as discussed above the formulation tested in the Declaration is not commensurate in scope with the instant claims. The claims are drawn to a percutaneous formulation comprising 5 components while the tested formulation of Example 1 comprises at least 11 components in specific concentrations. It remains the position of the Examiner that the combination of the '480 and '373 patents obviates the broad instant claims. For these reasons the claims remain obviated.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-

0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618